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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,868	08/17/2006	Christopher Luckhurst	06275-468US1 100949-1P US	4699

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FISH & RICHARDSON P.C.
P.O BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
CHANDRAKUMAR, NIZAL S	
ART UNIT	**PAPER NUMBER**
1625	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,868	LUCKHURST ET AL.	
	Examiner	Art Unit	
	Nizal S. Chandrakumar	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 12-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 12-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicants' election of the invention of claims 1-6, filed 01/05/2007 without traverse, is acknowledged.

Pursuant to the Applicants' request, the Examiner has considered elected claims 1-6 together with claims 12-21 present in the amended claim. In the amended claims, claims 7-8 and claim 11 were withdrawn and claims 9-10 were cancelled.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-6 and 12-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not contain description of the invention, and of the manner and process of making and using the invention, to enable any person skilled in the art to which it pertains. Examples of evidence of lack of enablement are in the description for the preparation of a carboxylic acid, INTERMEDIATE 6 (page 24 of specification) and the written description for the preparation of an amide, EXAMPLE 8 (page 27 of specification).

The preparation of the INTERMEDIATE 6, allegedly, involves heating in an autoclave, a solution of an aryl bromide in methanol and triethylamine to 90° C for 17h in carbon monoxide at 6 bar. The outcome of the reaction is said to be replacement of

bromide radical in the aryl bromide by a CO_2CH_3 moiety. This is an uncommon, unique reaction because such transformations usually require the use of organo-metallic catalysts. This was not disclosed in the specification.

The preparation of amide EXAMPLE 8, allegedly, involves treatment of an amine with a coupling agent EDCI, HOBT and DMAP and triethylamine in dichloromethane. Amides, in general, are formed by the reaction of carboxylic acid and amine in the presence of a coupling agent and tertiary amine catalyst. However, the written description claims to have produced amides without using any carboxylic acids.

3. Claims 1-6 and 12-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for few limited class of amides compounds, does not reasonably provide enablement for the generic class of amide compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The Examiner acknowledges that the formation of amides by reaction of an amine with an activated carboxylic acid derivative is mentioned in the specification (page 24 and page 31). However, the claims are extremely broad and encompass an extremely large class of compounds.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: breadth of the claims; nature of the invention; state of the prior art; amount of direction provided by the inventor; the level of predictability in the art; the existence of working examples; quantity of experimentation needed to make or use the

invention based on the content of the disclosure; and relative skill in the art. All of the factors have been considered with regard to the claim, with the most relevant factors discussed below:

The breadth of claims: Claims 1-6 and 12-21 are drawn to carboxylic amides, derived from a piperidine (amine) portion and a carboxylic acid (acid) portion. The amine portion has five main variables. The acid portion comprises of compounds derived from substituted aryl and substituted heteroaryl groups connected to the carboxylic group by bond, CH_2, or CH_2O. The substitutions on the aryl and heteroaryl groups include plurality of functionalities comprising OH, CO_2R^3, $CH_2CO_2R^3$, CH_2SO_3H, $OCH_2CO_2R^3$ or OCH_2SO_3H, hydrogen, halogen, cyano, nitro, hydroxy, NR^4R^5 C_{1-6} alkyl (optionally substituted with halogen), C_{1-6} alkoxy (optionally substituted with halogen), $S(O)_p$(C1-6 alkyl), $S(O)qCF_3$ or $S(O)_qNR^6R^7$; p and q being 0,1,2 and each R group further containing additional variables. In addition the claims encompass N-oxides, pharmaceutically acceptable salts and/or solvates thereof. Thus the claims are very broad, one that is not supported by instant specification.

The amount of direction provided by the inventor: The questionable description of INTERMEDIATE 6 (page 24) and EXAMPLE 8 (page 27) is mentioned above. In addition, the amount of direction provided by the specification for making the above mentioned 'amine' part is limited to Q=H; and W= CH_2 or O and is not applicable when Q =OH or when R_2 is H. The direction provided by the specification for making the above mentioned "acid" part is limited to Y = CO_2H, $CH_2CO_2CH_3$.

The presence of absence of working examples: The Examples indicated in the specification are applicable to compounds wherein Y = CO_2H, $CH_2CO_2CH_3$; Q = H and W= CH_2 or O. There are no working examples for Y = sulfur containing variables. There are no working examples for Q = OH. There is one example of a heteroaryl carboxamide, "prepared" by the above-mentioned method of EXAMPLE 8. There are no working examples of formation of N-oxides, pharmaceutically acceptable salts and/or solvates thereof.

The quantity of experimentation: The lack of working examples for formation amides from aryl and heteroaryl carboxylic acids with complex groups, such as CH_2SO_3H or OCH_2SO_3H, and lack of citation of sources for the functionalized starting material 'amines' and 'carboxylic' acids' would require a burdensome amount of research for one skilled in the art, to practice the invention.

The relative skill of those in the art: the skill of one of ordinary skill in the art is very high, e.g., Ph.D. and M.D. level technology.

Allowable Subject Matter

Claims 1-6 and 12-21 would be allowable if rewritten to overcome the 35 USC § 112 set forth in this office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nizal S. Chandrakumar whose telephone number is 571-272-6202. The examiner can normally be reached on 8.30 am – 5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached at 571-272-0670 or Primary Examiner D. Margaret Seaman can be reached at 571-272-0694. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nizal S. Chandrakumar

D. MARGARET SEAMAN
PRIMARY EXAMINER